

Europäisches Patentamt  
European Patent Office  
Office européen des brevets



(11) **EP 1 277 449 A1**

(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:  
22.01.2003 Bulletin 2003/04

(51) Int Cl.<sup>7</sup>: **A61F 2/06, A61L 31/16**

(21) Application number: **01830489.9**

(22) Date of filing: **20.07.2001**

(84) Designated Contracting States:  
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU  
MC NL PT SE TR**  
Designated Extension States:  
**AL LT LV MK RO SI**

• **Rolando, Giovanni**  
10034 Chivasso, Torino (IT)  
• **Curcio, Maria**  
13040 Saluggia, Vercelli (IT)  
• **Gaschinò, Paolo**  
10034 Chivasso, Torino (IT)

(71) Applicant: **SORIN BIOMEDICA CARDIO S.p.A.**  
13040 Saluggia (Vercelli) (IT)

(74) Representative: **Bosotti, Luciano et al**  
c/o **Buzzi, Notaro & Antonielli d'Oulx**  
Via Maria Vittoria 18  
10123 Torino (IT)

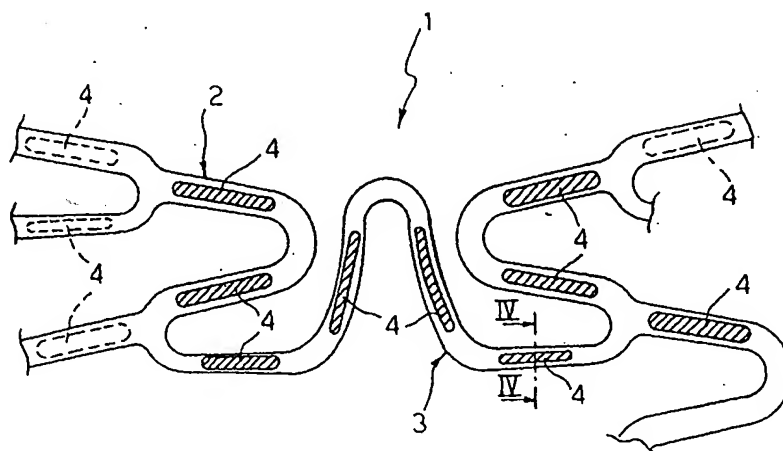
(72) Inventors:  
• **Vallana, Franco**  
10123 Torino (IT)

(54) **Stent**

(57) A stent (1) comprises a radially expandable tubular body made up of elements (2, 3) defining a reticular structure. The aforesaid elements (2, 3) constitute respective branches of the reticular structure and are at least locally provided with recesses (4) that are able to receive agents for the treatment of the site of implant of the stent (1). Where present, the aforesaid recesses (4) occupy a substantial portion, typically between 10% and 60% of the area of the overall cross-sectional area of the respective element. The recesses are made in such

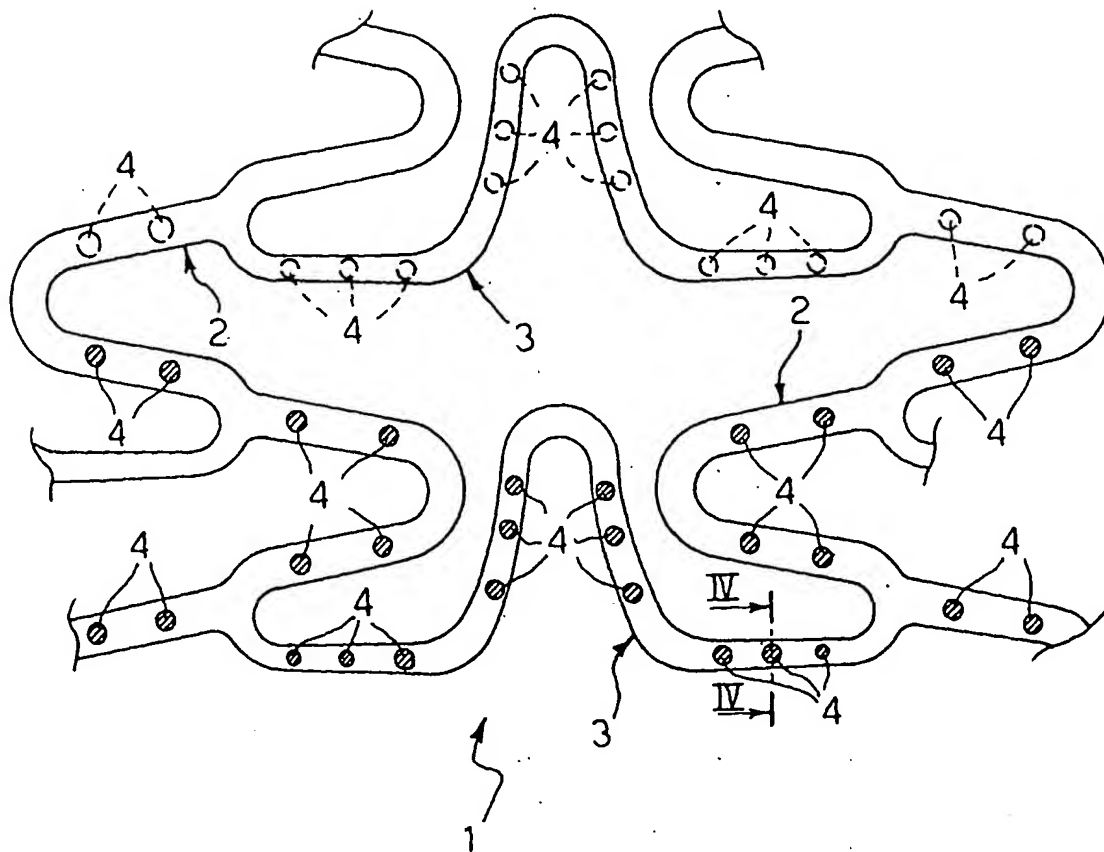
a way as to leave substantially unaltered the bending moments of the respective elements (3). The recesses (4) may be present continuously in a discontinuous way on said elements (2, 3) of said stent, the solutions of continuity, i.e., with solutions of continuity in the areas of the stent subjected to deformation during the radial expansion of the stent (1) itself. The recesses (4) may also have a general well-like conformation that enables distribution thereof in a selectively differentiated way on the surface of the stent (1).

**Fig. 2**



EP 1 277 449 A1

Fig. 3



## Description

[0001] The present invention relates to stents, a subject to which an extensive literature has been devoted.

[0002] The above applies also at a patent level, as is witnessed, for example by the documents EP-A-0 806 190, EP-A-0 850 604, EP-A-0 857 470, EP-A-0 875 215, EP-A-0 895 759, EP-A-0 895 760, EP-A-1 080 738, EP-A-1 088 528, and EP-A-1 103 234, all of which are assigned to the present applicant.

[0003] In particular, the present invention falls within the line of research aimed at developing solutions that enable the stent to be used as a vehicle for active or activatable agents of various nature (e.g., pharmacological agents, radioactive agents, etc.) designed, for example, to perform a function as restenosis antagonist. Solutions of this sort are described, in the framework of the documents cited above, in EP-A-0 850 604, EP-A-1 080 738, and EP-A-1 103 234.

[0004] In particular, EP-A-0 850 604 describes the possibility of providing, on the surface of a stent, in particular on its outer surface, a sculpturing having the function of increasing the surface area of the stent in such a way as to create undercuts and/or, in general, a surface roughness in order to facilitate application of coatings of active or activatable agents. The said sculpturing, consisting for instance of microspheres, may also favour adhesion of the stent to the wall of the vessel being treated.

[0005] The most recent clinical developments have revealed that limiting the intervention to coating the surface of the stent with active or activatable agents may come up against various difficulties and/or problems.

[0006] In the first place, the amount of agent with which the stent is coated may in actual fact prove insufficient, above all when the aim is to obtain a release, and hence an action, that is prolonged in time. To the above there is added the consideration that, in applications of vascular angioplasty, the surfaces of the stent, and above all the inner surface, are subjected to an action of flushing by the blood flow.

[0007] In the second place, also for the reason just mentioned, it is from many points of view desirable that the active or activatable agent should be made available and released prevalently, if not exclusively, on the outer surface of the stent, and not, instead, on its inner surface. This applies above all in the case where the agent applied on the stent is designed to perform an antagonistic function in regard to restenosis. The corresponding mechanism of action which is aimed at acting on the outer surface of the stent facing the wall of the vessel undergoing treatment may have unfavourable effects in areas corresponding to the inner surface; for example, phenomena of neointima formation on the inner surface of the stent, which are considered to be undoubtedly beneficial in the phases subsequent to the implant phase, may prove hindered.

[0008] In the above general framework, it would be

desirable to have available stents that may take on the configuration of actual reservoirs of active or activatable agents, possibly different from one another, available in sufficient quantities to achieve a beneficial effect that may even be prolonged over time, together with the further possibility of making available agents that are even different from one another, located selectively in different positions along the development of the stent, with the additional possibility of selectively varying the dosages in a localized way, for instance achieving dosages that are differentiated in the various regions of the stent.

[0009] On the other hand, it should not be forgotten that a stent is always and in any case configured as a structural element, in the sense that, once placed in the implantation site and brought into its radially expanded condition, the stent must be able to maintain the perviousness of the treated vessel without being subject to appreciable phenomena of contraction or collapse deriving from the radial compressive loads applied on the stent by the walls of the treated vessel.

[0010] This explains why the known solutions, aimed at creating on the surface of the stent superficial irregularities such as might enable anchorage of coatings and/or agents of various nature, have so far involved only quite a contained portion of the cross section of the parts (radially expandable annular elements, longitudinal elements of connection) of which the stent is normally composed.

[0011] The purpose of the present invention is to make a stent of an improved type which is able to reconcile in an optimal way the characteristics of longitudinal flexibility, which are required, for example, during the phase in which the stent is made to advance towards the implantation site, with the characteristics of plastic behaviour required for the stent to be able to perform an altogether effective action of support after being expanded or dilated, minimizing and virtually eliminating any phenomena of recoil.

[0012] The object of the present invention is thus to provide a solution that is able to overcome in a decisive way the difficulties and drawbacks referred to above.

[0013] According to the present invention, the aforesaid purpose is achieved thanks to a stent having the characteristics specified in the annexed claims.

[0014] It will be appreciated that in the present description and in the annexed claims the term "stent" is used in its widest sense, referring in general terms to any device having an overall tubular shape which is able to maintain in conditions of perviousness a segment of a blood vessel or any other anatomic lumen.

[0015] It therefore follows that the scope of the invention must not in any way be understood as being limited to stents for vascular angioplasty. The range of possible application of the invention extends, for example, to stents for reducing aneurysmatic phenomenon of various nature and/or to the so-called "stent-grafts".

[0016] In particular, the solution according to the invention is suitable for being applied to particular advan-

tage in stents designed to be provided, at least on part of their surfaces, with a coating of biocompatible carbon material of the type described, for instance, in the documents US-A-5 084 151, US-A-5 133 845, US-A-5 370 684, US-A-5 387 247, and US-A-5 423 886.

[0017] The invention will now be described, purely by way of a non-limiting example, with reference to the annexed drawings, in which:

- Figure 1 illustrates a first possible embodiment of the solution according to the invention;
- Figures 2 and 3 illustrate a further two possible embodiments of the solution according to the invention;
- Figure 4 reproduces at an enlarged scale for greater clarity a sectional view according to the line IV-IV reproduced in Figures 1 to 3,
- Figures 5 to 8 illustrate different possible variants embodiments of the invention; and
- Figure 9 is a schematic illustration of a particular mode of use of the invention.

[0018] In Figures 1 to 3, the reference number 1 designates part of the structure of any known type of stent, comprising a radially expandable tubular body made up of elements defining a reticular structure.

[0019] The above may be, for instance, a stent of the type illustrated in the document EP-A-0 875 215.

[0020] The said stent, which is not herein illustrated as a whole, generally comprises a plurality of annular elements having a roughly cylindrical shape and a serpentine pattern, which are designed to be aligned in sequence along the main axis of the stent. The above structure (which is to be held altogether known) is schematically illustrated for reference in the top part of Figure 9, where the longitudinal axis of the stent is denoted, according to the prevalent conventions, as z axis.

[0021] The various annular elements 2 are connected together by means of longitudinal connection elements 3, generally referred to as "links" and have, in the example of embodiment herein illustrated, a general lambda configuration. Preferably, and according to a configuration in itself known, the connection elements 3 are connected to the cylindrical elements 2 at the "0" points of the respective sinusoidal paths. The elements 2 and 3 described above thus constitute respective branches of the reticular structure of the stent 1.

[0022] The geometrical particulars of the stent 1 do not, however, constitute a limiting or binding element of the invention; the solution according to the invention can, in fact, be applied to stents of any type, shape or dimensions. Even though the invention has been developed with particular attention paid to the possible use in the sector of stents obtained starting from a microtube, the solution according to the invention can also be applied to stents obtained, for instance, starting from variously shaped filiform materials (the so-called "wire" stents).

[0023] The solution according to the invention is based upon the realization of the fact that the characteristics of structural strength of the parts constituting the stent (in the example of embodiment herein illustrated, the annular elements 2 and the links 3) are not generally impaired even when the cross section of the said elements is - even markedly - hollowed out, provided that the formation of the corresponding hollow parts or recesses is such as not to jeopardize the characteristics of flexural strength of said elements, the said characteristics being identified in particular by the corresponding bending moments of inertia.

[0024] Figures 1 to 3 illustrate three different modalities of possible embodiment of the solution according to the invention.

[0025] In all three cases it is envisaged that the elements 2 and 3 of the stent, which have in general a filiform or bar-like configuration (or, resorting to a more appropriate term drawn from structural mechanics, a "beam" configuration) are subjected to an action of reduction of their section, obtaining in the parts themselves, and preferably on the surfaces facing the outside of the stent 1, recesses, designated as a whole by 4. The recesses 4 are able to receive respective fillings A (Figure 4) of active or activatable agents of various nature (for example, pharmacological agents, radio-active agents, etc.) designed, for instance, to perform a restenosis-antagonist function.

[0026] In the embodiment illustrated in Figure 1, the recesses in question may basically amount to a single recess which extends practically without any discontinuities over the entire development of the stent 1.

[0027] The embodiment represented in Figure 2 envisages, instead, that the recesses 4 are chiefly, if not exclusively, made in areas corresponding to the rectilinear or substantially rectilinear portions of the parts 2 and 3, avoiding in particular both the curved parts (for example, the cusp parts of the sinusoidal path of the elements 2, the cusp part of the central loop of the links 3, and the areas of connection of the central loop to the side branches of the links 2 themselves) and the areas in which the links 3 are connected to the elements 2.

[0028] The above-mentioned cusp and/or connection parts correspond, in fact, to the areas that are to undergo deformation during normal operation of the stent, and in particular during expansion of the stent from the radially contracted implant condition to the radially expanded condition in which the stent supports the vessel.

[0029] In other words, in the embodiment of Figure 2 the formation of recesses 4 is limited just to the areas of the elements 2 and 3 that will be less subject to stress during operation of the stent.

[0030] The embodiment of Figure 3 relates, instead, to the possibility of making the recesses 4 in the form of separate wells set at a distance apart from one another and variously distributed over the surface of the stent 1.

[0031] As may be clearly seen, the representation of Figures 1 to 3 highlights characteristics of implementa-

tion that may also be used in combination with one another. For example, according to the specific requirements of application and treatment, it is possible to envisage that in certain parts of the stent the solution represented in Figure 1 will be adopted, resorting, instead, in other areas of the stent to solutions of the type represented in Figures 2 and 3. All three solutions represented in the figures may therefore be freely combined with one another even in a single stent.

**[0032]** The solutions represented in Figures 2 and 3, in which the recesses 4 consist of hollowed-out formations separate from one another prove particularly advantageous in those applications in which the recesses 4 are designed to function as reservoirs to enable arrangement of active/activatable agents of a different nature on the stent 1.

**[0033]** For example, with reference for reasons of simplicity to the solution illustrated in Figure 3, where this possibility is more evident, each of the wells constituting a respective recess 4 can receive within it an active/activatable agent having different characteristics. At least in principle, this solution makes it possible to have available on the stent, virtually and in principle, as many different agents as there are recesses 4.

**[0034]** Leaving to one side the above hypothesis, more commonly the recesses 4 of the solution illustrated in Figure 3 can be used to put different agents in different areas of the stent 1. For instance, the recesses located at the ends of the stent can receive anti-inflammatory agents since the end parts of the stent are the ones most exposed to the possible onset of inflammatory phenomena.

**[0035]** In any case, it is emphasized that the present invention relates primarily to the structure of the stent 1 and does not specifically regard the nature, characteristics, and dosages of the agents - which may be of any nature - that are to be accommodated in the recesses 4.

**[0036]** An important characteristic of the solution according to the invention is provided by the possibility, better illustrated in the cross-sectional view of Figure 4 (and in the views of Figures 5 to 8, which constitute respective variants), of obtaining the recesses 4 not only in the form of a surface sculpturing, but also in the form of cavities which occupy a substantial part of the cross-sectional area of the stent/part/element (in the example of Figure 4, this is one of the links 3) in which the recess 4 is made.

**[0037]** For instance, the recess illustrated in Figure 4 occupies a portion corresponding to approximately 30% of the overall section (more precisely, of the overall sectional area) of the surface of envelope of the cross section of the element considered.

**[0038]** The aforesaid percentage value is typically within the 10% - 60% range, preferably in the 20% - 50% range, and, even more preferably not less than 30%.

**[0039]** It will on the other hand be appreciated that the values and ranges of values herein indicated may be extended or modified without prejudice to the affects

pursued, as will be evident from the present description to a person skilled in the art.

**[0040]** In the embodiment illustrated in Figure 4, the above-mentioned recess has an approximately rectangular profile, so that the "full" part of the element 3 in which the recess 4 is made has a generally C-shaped pattern. An overall C-shaped pattern may be encountered also in the elements 3 illustrated in the variants of Figures 5 to 8. The aim here has been to highlight the fact that the recess 4 (which in the figure has an approximately rectangular development, with the main dimension in the direction of the width of the element 3, i.e., in a direction that is tangential to the stent 1) may have profiles of a different type.

**[0041]** For example, this may be, as in the case of Figure 5, a recess with a rectangular cross-sectional profile, but with the larger dimension in the direction of the depth of the element 3, i.e., in the radial direction of the stent 1. Alternatively, it may be an overall U-shaped profile (Figure 6), or else a V-shaped profile (Figure 7), or yet again a profile such as to bestow on the element 3 a general channel-shaped pattern with an inlet part of the recess 4 that has dimensions smaller than the maximum dimensions of the recess 4 itself, according to a general "undercut" configuration (Figure 8). Of course, it is also possible to make the recesses 4 in such a way that, instead of being blind as in the case of all the examples illustrated herein, they at least marginally pass through the body of the respective element 3.

**[0042]** Tests carried out by the present applicant have shown that, if techniques in themselves known are resorted to (such as chemical etching, the use of physical etching agents, for example laser-beam or ion-beam etching), it is possible to make, in the elements 3, recesses 4 the sectional area of which ranges from 10% to 60% of the overall sectional area of the envelope of the element considered, without detriment to the characteristics of structural strength, and hence functionality, of the elements 2 and 3, provided that the recess 4 is obtained according to modalities that do not produce an appreciable reduction in the bending moments of inertia (measured both in the radial direction and in the tangential direction with respect to the development of the stent) of the element 2, 3 considered.

**[0043]** Of course, the aforesaid effect of reduction of the section and conservation of the moments of inertia is with reference to the cross section (see the cross-sectional line IV-IV of Figures 1 to 3) measured in the area in which the recess 4 is obtained.

**[0044]** In particular, in the case of the embodiment of Figure 1, the recess 4 is present practically throughout the development of the stent, so that the condition referred to above must be encountered practically throughout the structure of the stent.

**[0045]** In the embodiment of Figure 2, the aforesaid condition is to be respected in the areas of extension of the recesses 4, this condition being, on the other hand, automatically met in the rounded end areas of the re-

cesses 4 themselves.

[0046] Finally, in the case of the well-shaped recesses 4 represented in Figure 3, the aforesaid condition must be satisfied in the maximum diametral plane of the recess. Also in this case, once this condition has been met in the aforesaid maximum sectional plane, it is automatically satisfied also in the other sectional planes.

[0047] What has been said in regard to the well-shaped recesses of Figure 3 of course also applies to recesses (not specifically illustrated in the drawing, but comprised in the scope of the present invention) which envisage areas of variable cross section throughout the longitudinal development of the recess.

[0048] From an observation of the cross-sectional view of Figure 4 it is possible to realize that the presence of recesses, preferably made on the outer surface of the stent, enables arrangement of a wide reservoir for gathering active/activatable agents A that can be released from the stent to the adjacent tissue.

[0049] Since the recesses 4 are made preferably in the outer surface of the stent, the phenomenon of release may take place preferably in a centrifugal direction, i.e., from the outside of the stent 1 towards the wall of the vessel undergoing treatment, thus containing to a very marked extent the phenomena of possible diffusion in a radial direction towards the inside of the stent 1. In this way it is possible to prevent undesired antagonistic phenomena in regard to the possible neointima formation, such as the neointima structure indicated by NI in Figure 4 alone.

[0050] The fact of having available recesses 4 of large dimensions (and not ones already limited to a modest surface roughness of the stent) renders less critical the aspect linked to the physical anchorage of the agent or agents to the surface of the stent.

[0051] It may indeed be stated that the solution according to the invention makes it possible to pass from a logic of pure and simple "coating" of the stent to an approach that envisages the use of the stent 1 itself as a true container/supplier of active/activatable agents, at the same time with the possibility of relying upon a true effect of containment rendered still more marked in the case where, as illustrated in Figure 8, the recess 4 can be made in undercut conditions, hence with an effect of mechanical retention of the agents A within the recess.

[0052] The diagram of Figure 9 shows how different agents A1, A2, A3 may be distributed, for example exploiting the different spatial distribution of the well-shaped recesses illustrated in Figure 3 and/or playing upon the modalities of filling of the recesses with the agents in question so as to present levels of concentration X1, X2, X3 differentiated along the longitudinal development of the stent.

[0053] In particular, the diagram of Figure 9 illustrates the possible use of a first agent A1 (for example, an anti-inflammatory agent) with a higher concentration at the ends of the stent as compared to the central area of the stent. There is then illustrated the possibility of distrib-

uting another agent A2 (for example, an anti-mitotic agent) with a level of concentration X2 that is constant throughout the longitudinal development of the stent. Finally, the possibility is represented of distributing yet another agent A3 (for example, a cytotoxic agent) with a maximum level of concentration in the central area of the stent and levels of concentration that progressively decrease towards the ends of the stent.

[0054] In addition, Figure 4 illustrated the fact that, according to a particularly preferred embodiment of the invention, the entire surface of the stent (with the possible exclusion of the surface of the recess 4, even though this fact is not of particularly determining importance) may be coated with a layer of biocompatible carbon material 41 having the characteristics, and applied according to the modalities, described in the various US documents cited in the introductory part of the present description.

[0055] A coating of carbon material of this sort performs an anti-thrombogenic function, favouring endothelization and - a factor that is deemed of particular importance - acting in the direction of preventing release of metal ions from the stent 1 to the surrounding tissue.

[0056] As regards the technologies of implementation, the recesses 4 may be made, as has already been said, starting from a pre-existing stent structure, and then obtaining (using chemical, physical and/or mechanical means) an action of removal of material aimed at producing the formation of the recesses 4.

[0057] In an embodiment that has proved particularly advantageous, relating to stents obtained starting from a microtube, the recesses 4 are made in the microtube before cutting of the stent is carried out.

[0058] Of course different embodiments are possible. For example, in the case of wire stents, a sectional profile of the type illustrated in Figures 4 to 8 can be obtained by drawing when the wire is being made.

[0059] As regards the choice of the sectional profile which is determined by the formation of the recesses 4, the general C-shaped profile of the element 3 represented in Figures 4 to 8, whilst constituting a preferred choice, is not an imperative choice. For example, it is possible to adopt profiles of different section, for example an H-shaped section, an L-shaped section, or a T-shaped section.

[0060] The C shape proves preferential in so far as it enables the recess 4 to be obtained in such a way that it emerges directly and exclusively on the outer surface of the stent.

[0061] As regards the definition of the dimensions of the recesses 4, it is to be recalled that the percentage values indicated herein refer in general to the ratio between the sectional area corresponding to the recess 4 and the overall sectional area of the envelope of the element of the stent in which the recess is made, including also the sectional area of the recess.

[0062] As compared to traditional embodiments, hence ones with elements 2, 3 having a full section (i.

e., without recesses such as the recesses 4), the elements of a stent made according to the present invention may present a sectional area that is possibly oversized with respect to the homologous sectional areas of the "full" elements of traditional stents.

[0063] In this connection, a number of examples of possible application of the solution according to the invention are given in what follows.

#### Reference example

[0064] Reference is made to an element 3 (see Figure 4) having a full square section of 120x120 micron (14400 square micron), the micron ( $10^{-6}$  metres) constituting the typical unit of measurement to which reference is made when determining the dimensions of the component parts of a stent.

[0065] An element of this sort may be coated by means of dipping in a substance such as a polymer, which can function as a carrier of active agents.

[0066] Tests currently carried out show that the maximum thickness of substance that can be deposited and withheld on the element 3 is in the region of 20 micron.

[0067] This means that the layer of substance facing the outside of the stent and able to perform an effective action has a sectional area of approximately 2400 square micron.

#### Comparative example 1

[0068] In an element 3 having the dimensional characteristics of the full element of the reference example, a continuous recess 4 was dug by means of laser etching according to the general geometry represented in Figure 4.

[0069] The recess in question had a depth (measured in the radial direction with respect to the stent) of 60 micron and a width (measured in the direction tangential to the stent) of 40 micron.

[0070] The recess in question thus occupied a portion corresponding to approximately 17% of the overall sectional area of the element and was able to receive inside it the same quantity of active substance as in the reference example (sectional area corresponding to approximately 24000 square micron).

[0071] The bending moments of inertia  $I_x$  and  $I_y$  of the element 3 provided with the recess, determined, respectively with reference to;

- an X axis oriented in a direction that is transverse and tangential with respect to the stent, and
- a Y axis oriented in a direction that is radial with respect to the stent,

were found to be respectively equal to 80% and 98% of the homologous moments of inertia (identical to one another, given the square section) of the element of the reference example.

[0072] The moments of inertia given above are understood as being referred to centroidal axes.

#### Comparative example 2

[0073] A recess having the same sectional area as the recess of the comparative example 1 was made in an element 3, the external dimensions of which were increased to 140 micron in height (measured in the radial direction with respect to the stent) and 120 micron in width (measured in the direction orthogonal to the height), so as to have an area of metal section, and hence characteristics of resistance to longitudinal stresses, corresponding to those of the element 3 of the reference example (14400 square micron). In this case, the recess occupied a portion corresponding to approximately 14% of the overall sectional area of the element.

[0074] The moments of inertia  $I_x$  and  $I_y$ , determined according to the same modalities seen previously, were, respectively 116% and 112% of the homologous moments of inertia of the element of the reference example.

#### Comparative example 3

[0075] A recess having a rectangular section with a sectional area twice the sectional area of the recess of the comparative example 1 was made in an element 3, the external dimensions of which were 160 micron in height (measured in the radial direction with respect to the stent) and 120 micron in width (measured in the direction orthogonal to the height), so as to have, also in this case, an area of metal section equal to that of the element 3 of the reference example (14400 square micron).

[0076] In this case, the recess (depth, 80 micron; width, 60 micron) occupied a portion corresponding to approximately 25% of the overall sectional area of the element.

[0077] The moments of inertia  $I_x$  and  $I_y$ , again determined according to the same modalities seen previously, were, respectively 160% and 125% of the homologous moments of inertia of the element of the reference example.

#### Comparative example 4

[0078] A recess having a substantially rectangular section with a sectional area of 8000 square micron, i. e., approximately 3.3 times the sectional area of the recess of the comparative example 1, was made in an element 3, the external dimensions of which were 140 micron in height (measured in the radial direction with respect to the stent) and 160 micron in width (measured in the direction orthogonal to the height), so as to have, also in this case, an area of metal section equal to that of the element 3 of the reference example (14400 square micron).

[0079] In this case, the recess (depth, 80 micron;

width, 100 micron) occupied a portion corresponding to approximately 36% of the overall sectional area of the element.

[0080] The moments of inertia  $I_x$  and  $I_y$ , again determined according to the same modalities seen previously, were, respectively 122% and 240% of the homologous moments of inertia of the element of the reference example.

[0081] The comparative examples seen previously hence prove the possibility of providing, at least locally, the elements 2 and 3 defining the structure of a stent with recesses 4 for receiving agents for treatment of the site of implantation of the stent. The foregoing in conditions whereby the recesses 4 occupy a substantial portion of the sectional area of the respective element, at the same time obtaining that the geometry of the recesses 4 leaves substantially unaffected the characteristics of bending strength of the respective element 2, 3, the said characteristics being identified mainly by the corresponding bending moments of inertia  $I_x$  and  $I_y$ .

[0082] The above applies in particular when the intervention is aimed at preserving the metal sectional area of the element in which the recesses are provided. The comparative examples seen previously prove that, operating in the above way, it is indeed possible to obtain increments - even marked ones - in the aforesaid bending moments of inertia.

[0083] Of course, without prejudice to the principle of the invention, the details of construction and the embodiments may vary widely with respect to what is described and illustrated herein, without thereby departing from the scope of the present invention as defined in the annexed claims.

#### Claims

1. A stent (1) comprising a radially expandable tubular body made up of elements (2, 3) defining a reticular structure, said elements (2, 3) constituting respective branches of the structure, **characterized in that** said elements (2, 3) are at least locally provided with recesses (4) for the reception of agents for the treatment of the site of implant of the stent, said recesses conferring on the respective element (2, 3), where said recesses are present, a hollowed sectional profile, of which said recesses (4) occupy a substantial portion; the geometry of said recesses (4) being such as to leave substantially unimpaired the characteristics of bending strength ( $I_x$ ,  $I_y$ ) of the respective element (2, 3).
2. The stent according to Claim 1, **characterized in that**, where present, said recesses occupy a portion between 10% and 60% of the sectional area of the respective element (3).
3. The stent according to Claim 1, **characterized in**

**that**, where present, said recesses occupy a portion between 20% and 50% of the sectional area of the respective element (3).

4. The stent according to Claim 1, **characterized in that**, where present, said recesses occupy a portion of not less than 30% of the sectional area of the respective element (3).
5. The stent according to any one of the preceding claims, **characterized in that** said recesses (4) are provided on the outside of the stent (1).
6. The stent according to any one of the preceding claims, **characterized in that** said recesses (4), where present, confer on the respective element (2, 3) a general C profile.
7. The stent according to any one of the preceding claims, **characterized in that** said recesses (4) have a substantially rectangular profile, with a greater dimension extending in a direction tangential to the stent (1).
8. The stent according to any one of the preceding claims from Claim 1 to Claim 6, **characterized in that** said recesses (4) have a substantially rectangular profile, with a greater dimension extending in a direction radial with respect to the stent (1).
9. The stent according to any one of the preceding claims from Claim 1 to Claim 6, **characterized in that** said recesses (4) have a general U-section profile.
10. The stent according to any one of the preceding claims from Claim 1 to Claim 6, **characterized in that** said recesses (4) have a general V-section profile.
11. The stent according to any one of the preceding claims, **characterized in that** said recesses (4) have, at least locally, a sectional profile with undercut areas.
12. The stent according to any one of the preceding claims, **characterized in that** said recesses (4) are present with substantial continuity on the elements (2, 3) of said stent.
13. The stent according to any one of the preceding claims from Claim 1 to Claim 11, **characterized in that** said recesses (4) are present in a discontinuous way on said elements (2, 3) of said stent, the solutions of continuity being located in the areas of said elements subjected to deformation during the deformation of said stent (1).



14. The stent according to any one of the preceding claims from Claim 1 to Claim 11, **characterized in that** said recesses (4) have a general well-like conformation.
15. The stent according to any one of the preceding claims, **characterized in that** it is provided, at least locally, with a coating of biocompatible carbon material (41).
16. The stent according to Claim 15, **characterized in that** said coating (41) extends also over the surface of said recesses (4).
17. The stent according to any one of the preceding claims, **characterized in that** a filling (A) of agent for the treatment of the site of implant of the stent, said filling (A) being placed in said recesses (4).
18. The stent according to Claim 17, **characterized by** fillings of different agents (A1, A2, A3) received in said recesses (4).
19. The stent according to Claim 18 or Claim 19, **characterized in that** said filling of at least one agent (A) is present with non-uniform distribution along the longitudinal development (Z) of the stent (1).

5

10

15

20

25

30

35

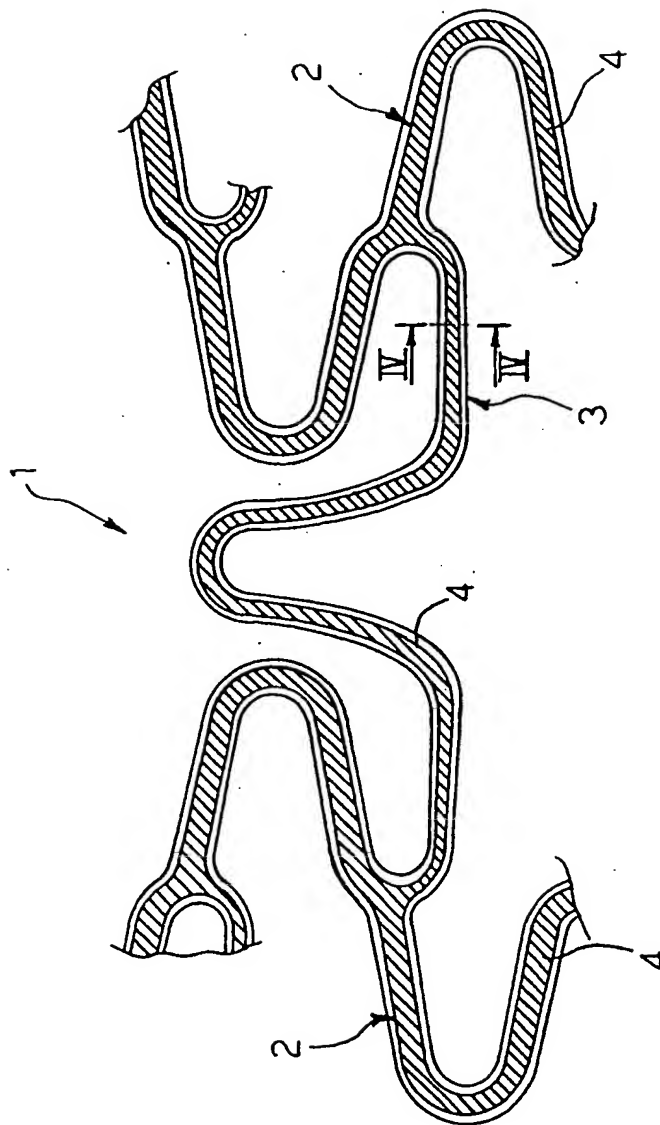
40

45

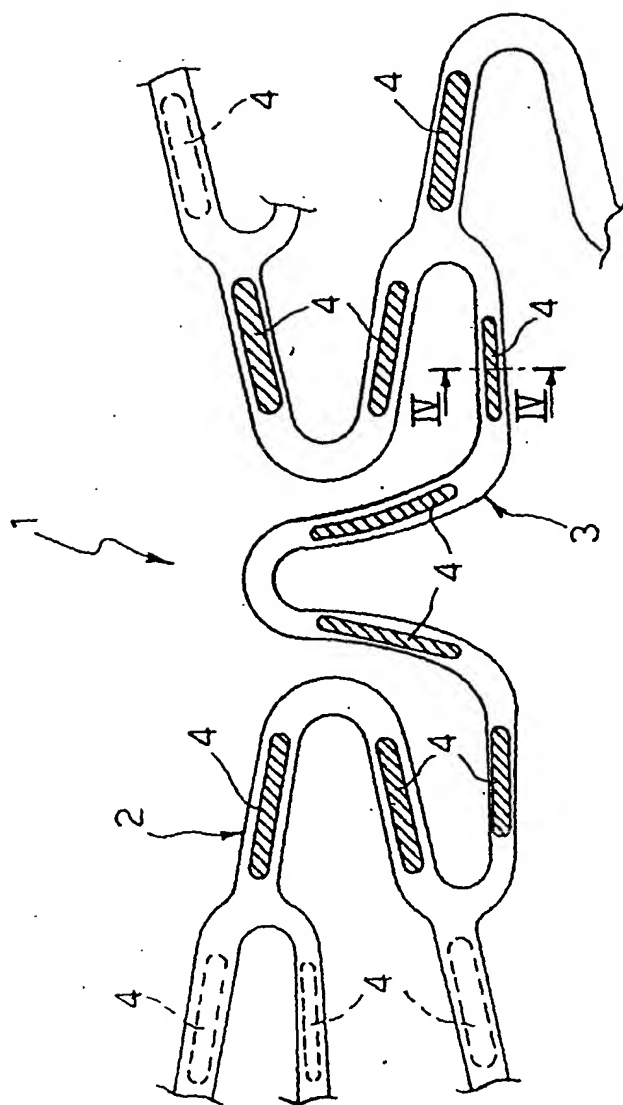
50

55

Fig. 1



2. 1. 1.



FiO-3

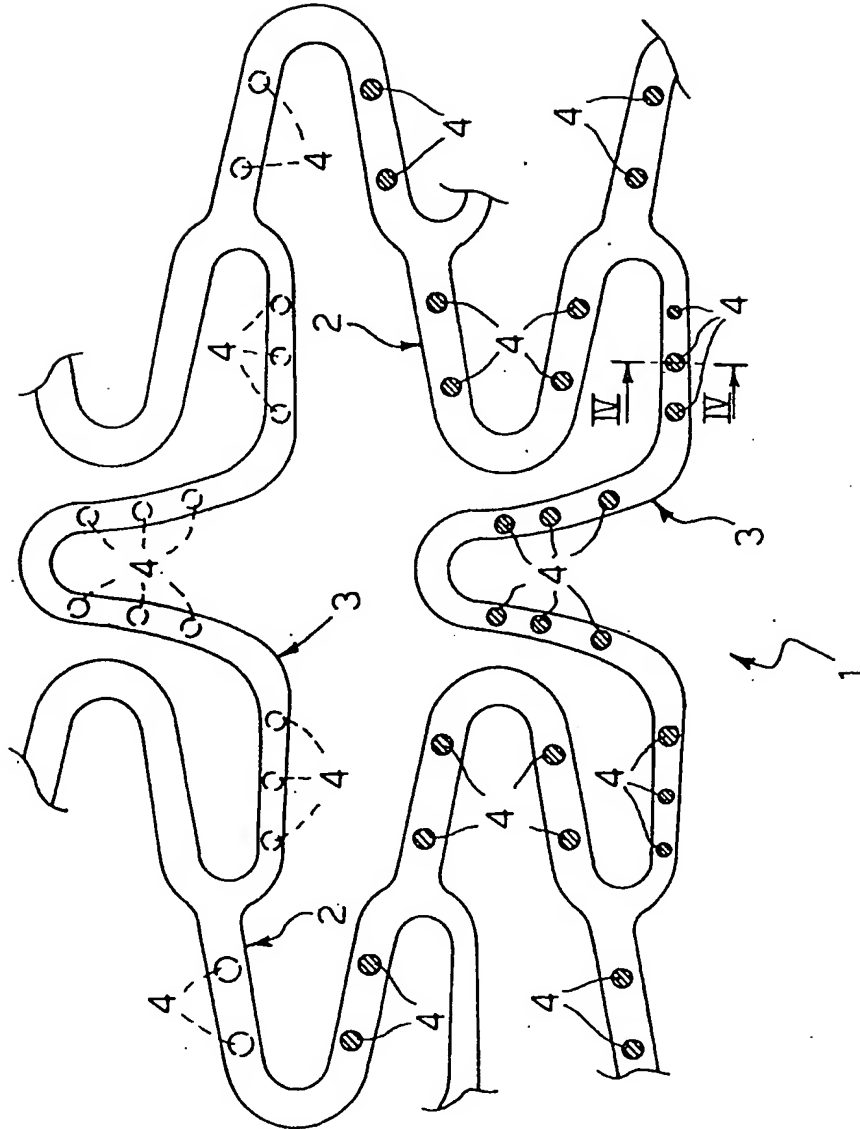


Fig. 4

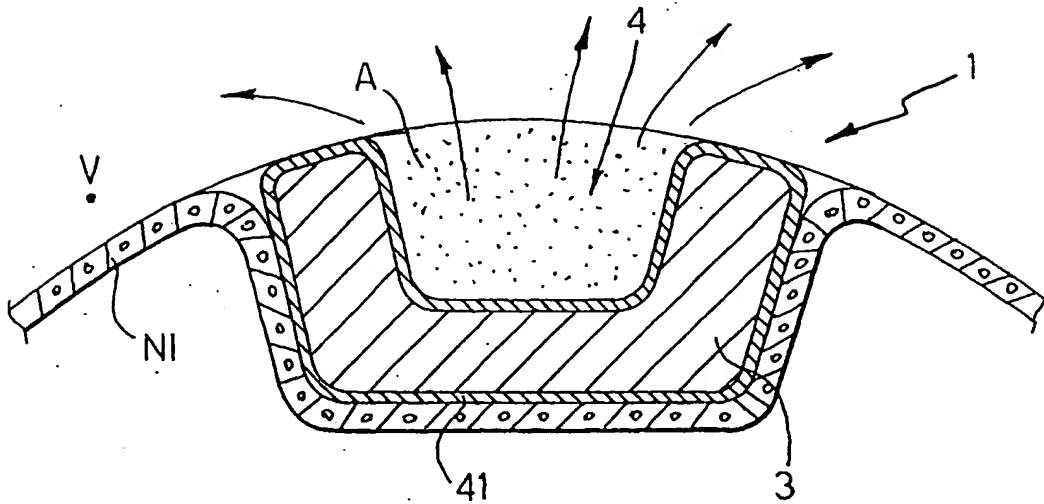


Fig. 5

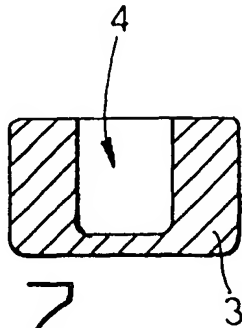


Fig. 6

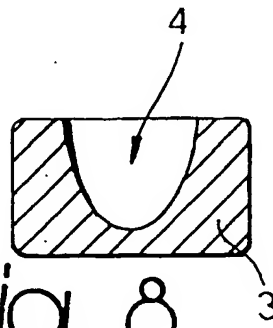


Fig. 7

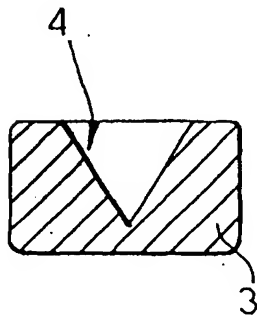


Fig. 8

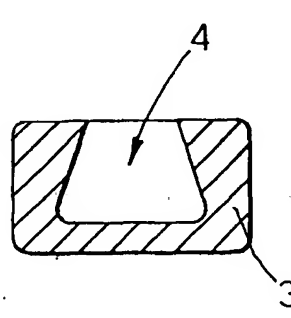
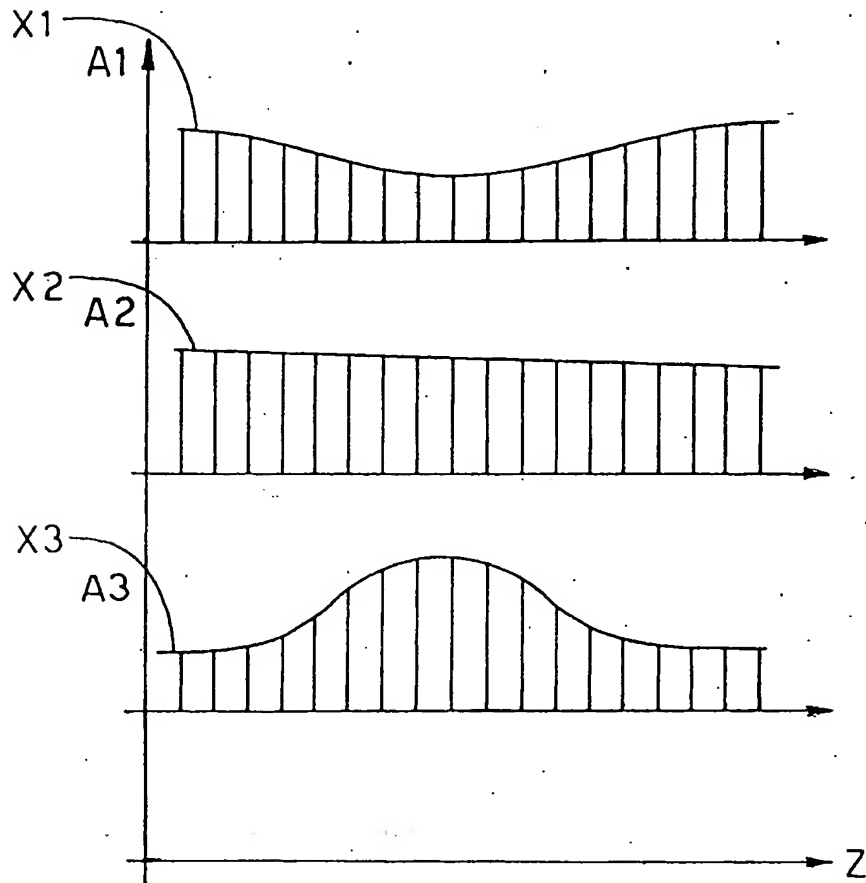
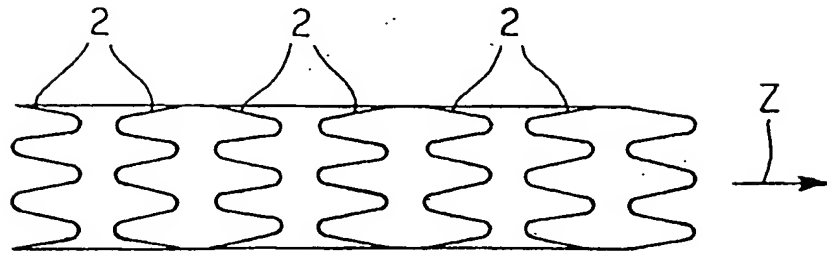


Fig. 9





European Patent  
Office

## EUROPEAN SEARCH REPORT

Application Number  
EP 01 83 0489

| DOCUMENTS CONSIDERED TO BE RELEVANT  |  |                                  |   |
|--|--|----------------------------------|---|
| Category   | Citation of document with indication, where appropriate, of relevant passages  | Relevant to claim                | CLASSIFICATION OF THE APPLICATION (Int.Cl.7)            |
| X  | WO 01 17577 A (ADVANCED CARDIOVASCULAR SYSTEM) 15 March 2001 (2001-03-15)<br><br>* page 6, line 28 - page 9, line 5; figures *<br>* page 13, line 21 - page 14, line 19 *  | 1-5, 8,<br>11, 12,<br>15-18      | A61F2/06<br>A61L31/16                                   |
| A  | ----   | 7                                |   |
| X  | US 6 254 632 B1 (SANDERS-MILLARE DEBORRA ET AL) 3 July 2001 (2001-07-03)<br><br>* the whole document *   | 1-5, 11,<br>13, 14,<br>17, 18    |   |
| A  | ----   | 6, 9, 10,<br>15, 16, 19          |   |
| X  | EP 0 950 386 A (CORDIS CORP)<br>20 October 1999 (1999-10-20)<br><br>* paragraph '0015! - paragraph '0016!;<br>claims; figures *<br>* paragraph '0034! - paragraph '0035! * | 1, 5, 7,<br>13, 14,<br>17, 19    |   |
| A  | ----   | 2-4, 15,<br>16                   | TECHNICAL FIELDS<br>SEARCHED (Int.Cl.7)<br>A61F<br>A61L |
| A  | WO 98 23228 A (ALZA CORP)<br>4 June 1998 (1998-06-04)<br>* page 8, line 30 - page 9, line 5;<br>figures *<br>-----   | 1, 5, 6,<br>12, 17, 18           |   |
| The present search report has been drawn up for all claims   |  |                                  |   |
| Place of search  |  | Date of completion of the search | Examiner  |
| THE HAGUE  |  | 20 December 2001                 | Neumann, E  |
| CATEGORY OF CITED DOCUMENTS<br>X : particularly relevant if taken alone<br>Y : particularly relevant if combined with another document of the same category<br>A : technological background<br>O : non-written disclosure<br>P : intermediate document<br>T : theory or principle underlying the invention<br>E : earlier patent document, but published on, or after the filing date<br>D : document cited in the application<br>L : document cited for other reasons<br>& : member of the same patent family, corresponding document |  |                                  |   |

EPO FORM 1503 03 B2 (P04C01)

**ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.**

EP 01 83 0489

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on  
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

20-12-2001

| Patent document<br>cited in search report |    | Publication<br>date | Patent family<br>member(s) |               | Publication<br>date |
|---|----|---------------------|----------------------------|---------------|---------------------|
| WO 0117577                                | A  | 15-03-2001          | US                         | 6287628 B1    | 11-09-2001          |
|   |    |                     | AU                         | 6941800 A     | 10-04-2001          |
|   |    |                     | WO                         | 0117577 A1    | 15-03-2001          |
| -----                                     |    |                     |                            |               |                     |
| US 6254632                                | B1 | 03-07-2001          | NONE                       |               |                     |
| -----                                     |    |                     |                            |               |                     |
| EP 0950386                                | A  | 20-10-1999          | US                         | 6273913 B1    | 14-08-2001          |
|   |    |                     | EP                         | 0950386 A2    | 20-10-1999          |
|   |    |                     | US                         | 2001029351 A1 | 11-10-2001          |
|   |    |                     | US                         | 2001027340 A1 | 04-10-2001          |
| -----                                     |    |                     |                            |               |                     |
| WO 9823228                                | A  | 04-06-1998          | AU                         | 5266698 A     | 22-06-1998          |
|   |    |                     | WO                         | 9823228 A1    | 04-06-1998          |
|   |    |                     | US                         | 6071305 A     | 06-06-2000          |
| -----                                     |    |                     |                            |               |                     |

EPC COM P0456

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82